Compliance Policy Guide

Guidance for FDA Staff

Registration of Food Facilities
Under the
Public Health Security and Bioterrorism Preparedness and Response Act of 2002

Comments and suggestions regarding this Compliance Policy Guide (CPG) should be submitted to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with docket number 2003D-0562.

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U.S. Department of Health and Human Services
Food and Drug Administration
Office of Regulatory Affairs (ORA)
Center for Food Safety and Applied Nutrition (CFSAN)
Center for Veterinary Medicine (CVM)

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Office of Enforcement
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5600 Fishers Lane
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This guidance document represents the Food and Drug Administration's (FDA) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

Sec. 110.300: Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

INTRODUCTION:

The purpose of this document is to provide guidance on FDA's strategy for enforcing and otherwise achieving compliance with the requirements of the interim final rule for Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (68 Fed. Reg. 58894 (Oct.10, 2003) (codified at 21 CFR 1.225- 1.243)).

This is a revision of the compliance policy guidance document issued in December, 2003. It is intended for FDA personnel and is available electronically to the public. This guidance document represents the Agency's current thinking on registration of domestic and foreign facilities manufacturing/ processing, packing, or holding food for human or animal consumption in the United States. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternate approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

BACKGROUND:

Section 305 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) (PL 177-188) requires owners, operators, or agents in charge of domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States to register their facilities with FDA by December 12, 2003, unless the facility is exempted. A domestic facility must be registered whether or not food from that facility enters interstate commerce. Facilities that begin, after December 12, 2003, to manufacture, process, pack, or hold food for

human or animal consumption in the U.S. must be registered with FDA before beginning such activities.

The purpose of registration is to provide FDA with sufficient and reliable information about food and feed facilities. When used with the detention, record keeping, and prior notice provisions in sections 303, 306, and 307, respectively, of the Bioterrorism Act, registration will help provide FDA with information on the origin and distribution of food and feed products and thereby, aid in the detection and quick response to actual or potential threats to the U.S. food supply. Registration information also will help FDA notify firms that may be affected by the actual or potential threat. FDA estimates that the total number of food facilities that must register is approximately 420,000, approximately half of which are domestic.

The Bioterrorism Act, as implemented by the interim final rule for registration of food facilities (68 Fed. Reg. 58894; October 10, 2003; codified at 21 CFR Part 1, Subpart H), exempts the following from registration:

a. A foreign facility, if food from such facility undergoes further manufacturing/processing (including packaging) by another facility outside the U.S. A facility is not exempt under this provision if the further manufacturing/processing (including packaging) conducted by the subsequent facility consists of adding labeling or any similar activity of a *de minimis* nature. In such circumstances, the facility conducting the *de minimis* activity also must be registered.
b. Farms, which are establishments devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both. Washing, trimming of outer leaves of, and cooling produce are considered part of harvesting. The term "farm" includes:
    i. Facilities that pack or hold food, provided that all food used in such activities is grown, raised, or consumed on that farm or another farm under the same ownership; and
    ii. Facilities that manufacture/process food, provided that all food used in such activities is consumed on that farm or another farm under the same ownership.
c. Retail food establishments, which are establishments that sell food directly to consumers as their primary function. If an establishment's annual sales to consumers exceed its sales to non-consumers, the establishment is an exempt retail establishment. For purposes of this exemption, businesses are not considered consumers.
d. Restaurants, which are establishments that prepare and serve food directly to consumers for immediate consumption.
e. Nonprofit food establishments, which are charitable entities that prepare or serve food directly to consumers, or otherwise provide food for consumption by humans or animals in the U.S.
f. Fishing vessels, including those that not only harvest and transport fish but also engage in practices such as heading, eviscerating, or freezing intended solely to

prepare fish for holding on board a harvest vessel. Fishing vessels that otherwise engage in processing fish are required to register. "Processing" means handling, storing, preparing, shucking, changing into different market forms, manufacturing, preserving, packing, labeling, dockside unloading, holding, or heading, eviscerating, or freezing other than solely to prepare fish for holding on board a harvest vessel. Note that "dockside unloading" is intended to cover waterfront facilities that unload vessels and pack the catch for shipment to buyers, not the vessels from which the catch is unloaded. (See 60 FR 65096, 65114 to 65115, December 18, 1995.)

g. Facilities that are regulated exclusively, throughout the entire facility, by the U.S. Department of Agriculture under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*), the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*), or the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*)

Certain other establishments are not required to be registered because they do not manufacture/process, pack, or hold "food" as defined in the registration regulation (21 CFR 1.227(b)(4)). This definition excludes food contact substances (including packaging materials), as defined in § 409(h)(6) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 348(h)(6)), and pesticides as defined in 7 U.S.C. 136(u). Thus, facilities that manufacture/process, pack, or hold only food contact substances or only pesticides are not required to be registered.

FDA's list of registered facilities and registration documents submitted to FDA are not subject to disclosure under the Freedom of Information Act. In addition, any information derived from the agency's list or registration documents that would disclose the identity or location of a specific registered person is not subject to disclosure. These restrictions on the disclosure of registration information do not apply to any information obtained by means other than registration or information that has previously been disclosed to the public. The agency is developing procedures to assist its personnel regarding disclosure of § 415 registration information.

FDA has prepared guidance, in the form of a series of questions and answers, on the interim final registration rule. This guidance is available at: http://vm.cfsan.fda.gov/~dms/guidance.html.

POLICY:

The Bioterrorism Act makes failure to register a prohibited act under § 301 of the FD&C Act. In addition, the Bioterrorism Act added § 801(l) to the FD&C Act, which provides that if an article of food being imported or offered for import is from a facility for which registration has not been submitted as required by § 415 of the FD&C Act, the article is subject to hold until the registration violation is corrected. Unlike the registration requirements for drugs and devices that result in misbranding violations under § 502(o) of the FD&C Act, the failure of a food facility to be registered with FDA does not cause food from that facility to be adulterated or misbranded in violation of the FD&C Act.

Owners, operators, or agents in charge of domestic facilities that manufacture/process, pack, or hold food for human or animal consumption in the U.S. are required to register the facility with FDA (unless expressly exempted), whether or not food from the facility enters interstate commerce. FDA anticipates that it, or a state agency acting on its behalf, will discover a domestic facility's failure to be registered during a routine food safety inspection. During an inspection, the investigator should determine whether a facility has been registered, and whether all information in the registration is accurate and current. The investigator also should note the facility's failure to be registered (or the failure of mandatory registration information to be updated) in the establishment inspection report and bring such failure to the attention of the District Compliance Branch.

If an inspection uncovers a registration violation, the field investigator should advise the facility's management of the requirement to register (or the requirement to update mandatory elements of the registration) and provide the facility with a copy of FDA's booklet (dated November 2003), "What you need to know about Registration of Food Facilities", which includes the website for electronic registration (www.access.fda.gov) and the address of the FDA office from which a paper copy of the registration form (Form 3537) may be obtained.

For domestic facilities, after November 1, 2004, FDA plans to enforce the registration provision as appropriate in each situation. Circumstances which could merit regulatory action include a continuing failure to register, and a threat on the food supply that poses a threat of serious adverse health consequences or death to humans or animals. In addition, FDA may also consider the failure to register as an additional charge in an enforcement action that is based on other statutory violations.

For foreign facilities, FDA generally intends to enforce the registration requirement in accordance with the policies set out in CPG 110.310, "Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness Response Act of 2002" (revised November, 2004).

REGULATORY ACTION GUIDANCE:

In most circumstances, the failure of a facility, domestic or foreign, to be registered is a violation that can be readily corrected by the facility's owner, operator, or agent in charge. Electronic registration of covered facilities may be accomplished with minimal effort and the registrant will receive nearly instantaneously a registration number. Registration by paper, although it will likely require more time, is also relatively easy to accomplish. Accordingly, the ability to remedy the failure is relatively straightforward for both types of facilities.

After November 1, 2004, FDA intends to focus its enforcement of the prohibited act provision related to registration (§ 301(dd)) on two situations: where there is a continuing failure to register a facility following issuance of a Warning Letter and where agency inspection of an unregistered facility documents serious violations of other provisions of the FD&C Act.

District Offices are granted direct reference authority for issuance of Untitled Letters, in accordance with Chapter 4, Regulatory Procedures Manual, and the Untitled Letter/Warning Letter procedure issued on March 5, 2002, when all of the following are present:

- The facility manufactures/processes, packs, or holds food for human or animal consumption in the U.S. and it is clear that the facility is not exempt from the registration requirement;
- The establishment file documents that management at the facility have been advised orally or in writing of the duty of the owner, operator, or agent in charge to register the facility; and
- The District Office has verified that the facility is not registered.

Untitled Letters should request the owner, operator, or agent-in-charge of the facility to register the facility at issue within 30 working days.

At the end of the 30 working day period established in an Untitled Letter, if there is no response from the firm and the facility remains unregistered, the District Compliance Branch should promptly arrange a discussion with the Center about whether to issue a Warning Letter to the owner, operator, or agent in charge due to a continuing failure to register the facility. (The Center and the District Office may choose to involve the Office of the Chief Counsel in this discussion.) To arrange a discussion concerning a human food facility, contact CFSAN's Office of Compliance, Division of Enforcement (HFS-605); to arrange a discussion concerning feed or food for animals, contact CVM's Office of Surveillance and Compliance, Division of Compliance (HFV-230).

If a Warning Letter is subsequently issued and the owner, operator, or agent in charge does not register the facility after issuance of that letter, the District should consider making an injunction recommendation (enjoining the firm and the owner, operator, or agent in charge from violating § 301(dd)) to CFSAN or CVM, as appropriate.

Enforcement of § 301(dd) will also be considered for facilities that agency inspection shows have serious violations of other provisions of the Act. If an unregistered facility has other violations, the failure to register should be included in any Warning Letter addressing these violations and, if not remedied, should also be included as a count or charge in any follow-up injunction or prosecution recommendation.

MODEL UNTITLED LETTER:

Dear Responsible Official:

The Food and Drug Administration has determined that your facility is subject to the registration requirement in § 415 of the Federal Food, Drug, and Cosmetic Act (the Act) and our implementing regulation at 21 CFR Part 1, Subpart H. During an inspection of your facility located at _____ on _____, you were (or your representative was) advised of this requirement. The failure to register a facility as required is a prohibited act

under § 301 of the Act. Our records indicate that, to date, this facility has not been registered with FDA.

As a responsible official of a facility that manufactures/processes, packs, or holds food for human or animal consumption in the United States, you are responsible for ensuring that your overall operation and the products you distribute are in compliance with the law.

We request that the owner, operator, or agent in charge of this facility, or an individual authorized by this facility's owner, operator, or agent in charge, register the facility with FDA within 30 working days of the date of this letter. Registration may be accomplished on-line at http://www.access.fda.gov. We strongly encourage the use of electronic registration because it will result in an automatic confirmation of registration and automatic issuance of a registration number.

Alternatively, the owner, operator, or agent in charge of this facility, or an individual authorized by the facility's owner, operator, or agent in charge, may register the facility by mail or fax (e.g., if you do not have reasonable access to the Internet) using FDA's food facility registration form, Form 3537. This form may be obtained by calling the FDA Industry Systems Help Desk at 1-800-216-7331 or 301-575-0156, or by writing to the agency at the following address:

U.S. Food and Drug Administration, HFS-681
5600 Fishers Lane
Rockville, MD 20857

When completed, the form may be faxed to (301) 210-0247 or mailed to the address above. FDA will process registrations submitted by mail or fax and provide a facility's registration number using the same method used to submit the registration to FDA.

We request that you reply to this letter in writing within 30 working days. If you are unable to register this facility within 30 working days, please inform us of the reason for the delay and the timeframe within which you plan to register. Your response should be directed to _____ at the above address.

If you have any questions about this letter, please call this office at _____.

Sincerely yours,

District Director